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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/819,458	03/27/2001	Geoffrey S. Martin	2409.3273.3US	2544

57600 7590 02/24/2006

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EXAMINER

SIRMONS, KEVIN C

ART UNIT	PAPER NUMBER
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3767

DATE MAILED: 02/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/819,458

Applicant(s)

MARTIN ET AL.

Examiner

Kevin C. Sirmons

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-30 and 42-45 is/are pending in the application.
- 4a) Of the above claim(s) 30 and 43-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-29 and 42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Drawings (Fourth Time) Emphasis Added

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: a third aperture. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24-29, 31 and 42 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ekholmer U.S. Pat. No. 4,717,379.

Ekholmer discloses an outer tube having a proximal end and a distal end (6); an inner tube (5) having a proximal end and a distal end defining there within a first lumen (2), said inner tube having an outer diameter less than the inner diameter of said outer tube (fig. 3), said inner tube being disposed within said outer tube to define an interior space between the outside of said inner tube and the inside of said outer tube (fig. 3),

the inner diameter of said inner tube being sized as to accommodate an insertion guide wire having an outer diameter in a range from about 0.036 inches to about 0.038 inches (It is the examiner's position that the inner tube is sized to accommodate the aforementioned guide wire without destroying the device of Ekholmer. Furthermore, it would have been an obvious matter of design choice to change the dimension of the catheter and/or insertion guidewire (which is not claimed) so that the inner tube can accommodate an insertion guidewire, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955). Additionally, applicant has not disclosed that the dimensions of the guidewire solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with any guide wire sized to fit into Ekholmer's catheter; a first septum; a second septum; a second lumen; a third lumen; a tapered distal tip; a first, second and third (figs. 1-3); as to claims 26-29 and 31, (fig. 1-3);

As to claim 25, Ekholmer discloses a catheter substantially as claimed except for the size of the inner diameter of the inner tube is about 0.04 inches. It would have been an obvious matter of design choice to change the dimension of the catheter so that the inner tube, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955). Furthermore, applicant has not disclosed that the dimensions of the inner tube solves any stated

problem or is for any particular purpose and it appears that the invention would perform equally well the catheter as disclosed by Ekholmer.

Response to Arguments

Applicant's arguments filed 12/13/05 have been fully considered but they are not persuasive.

In response to applicant's arguments, the recitation an insertion guide wire has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

In response to applicant's argument that an insertion guide wire, a recitation of the intended use and/or functional language of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use or functional language, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

The examiner submits that applicant's preamble does not breath life and meaning into claim 24. Furthermore, the device of Ekholmer is fully capable of performing the functions set forth in claim 24.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the flexibility of a catheter or lack of flexibility of the catheter) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

As to applicant's arguments on page 15, with regard to claim 24, Ekholmer clearly discloses applicant's claimed subject matter as in complete detail as contained in independent claim 24. As clearly shown in Fig. 2. if a second lumen is selected (from axial passages 3) and a third lumen is selected (from axial passages 3) on an opposite side of the inner tube, a first and second septum including other septums clearly separate the interior space into axial passages. Applicant's claim language does not exclude another septum being positioned circumferentially between the first and second septum. Thus, Ekholmer absolutely discloses each and every element of the claim in as complete detail as is contained in the claim.

In response to applicant argument on page 16, it would appear that applicant's arguments supports the examiner's position that guide wires are used with the catheter as described by Ekholmer.

Applicant clearly states, "that a guidewire may irritate or otherwise damage a mucous membrane." Applicant's statement clearly implies that guide wires do not irritate the membranes all the time and that some guide wires may not irritate membranes at all. Further, applicant has misunderstood the rejection. Not only is the examiner stating that the device of Ekholmer can be used with a guidewire to be inserted into a body cavity, but it could also be used with a guidewire to be inserted into the cardiovascular system.

Again, as to applicant's arguments regarding the guidewire. First, applicant has not claimed a guidewire whatsoever! Further, the Examiner asserts that substantially the majority of catheters that have a lumen have the ability to be used with a guidewire. This fact clearly includes Ekholmer's catheter. Nowhere in Ekholmer does it indicate that a guidewire teaches away from the device or destroys the device.

As to claim 25, applicant has basically further defined a guidewire, which he has not claimed. Changing the size of catheters and/or guidewire is not novel or new and can be regarded as obvious as clearly shown in your current rejection. Basically, applicant's dimensions lack criticality.

As to claim 27, see (fig. 1-3); as to claim 29, the lumens disclosed have a C-shaped transverse cross section. Further, applicant is invited to choose any of the two septums shown in (figs 1 and 2), which are clearly coplanar and C-shaped and relied on for the rejection. Any combination of septums shown in fig. 2 will anticipated the claim.

As to claim 42, see above rejections and arguments.

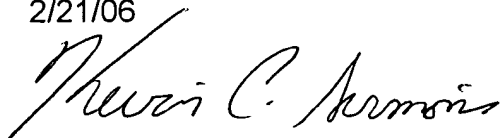
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin C. Sirmons whose telephone number is 571-272-4965. The examiner can normally be reached on Monday-Friday 6:30-4:00 ALT FRI.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kevin C. Sirmons
Primary Examiner
Art Unit 3767
2/21/06

A handwritten signature in black ink, appearing to read "Kevin C. Sirmons", is written over the printed name and title.